

In re Application of:
Rheins and Morhenn
Application No.: 09/375,609
Filed: August, 17, 1999
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PATENT
Attorney Docket No.: DERM1100-1

EXHIBIT A:

DECLARATION UNDER 1.132 (DR. NICHOLAS BENSON)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rheins and Morhenn Art Unit: 1646
Application No.: 09/375,609 Examiner: L. Spector
Filed: August 17, 1999
Title: METHODS AND KITS FOR OBTAINING AND ANALYZING SKIN
SAMPLES FOR THE DETECTION OF NUCLEIC ACIDS (as amended)

Commissioner of Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I, Nicholas R. Benson, do hereby declare and state that:

1. I am familiar with the above-identified patent application and the disclosure of methods for obtaining and analyzing skin samples therein.
2. I earned a Doctorate of Philosophy in Molecular Biology from University of Southern California, and was a Postdoctoral Fellow at the Department of Biology, University of Utah, Salt Lake City.
3. I am presently Vice President of Research and Corporate Development of Dermtech International, the licensee of the above-identified patent application.
4. I understand that claims 64, 65, 76, 85, 86, and 161-162 stand rejected under 35 U.S.C. § 102 as anticipated by Garofano et al., *Adv. Forensic Haemogenet.*, 6:281-83 (1996), and that claim 70 stands rejected as anticipated by, or in the alternative under 35 U.S.C. § 103, as obvious over Garofano et al.
5. I understand that claims 71-72 and 80-82 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Garofano et al.

6. I understand that claims 77-78, 80-83, 149-154, 156-158, and 163 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Garofano et al. in view of Paludan et al., *J. Invest. Derm.* 99:830-35 (1992).

7. I understand that claim 155 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Garofano et al. in view of Paludan et al., and further in view of Ramsay et al., U.S. Pat. No. 6,056,859 and Furcht et al., U.S. Pat. No. 6,054,277.

8. I understand that claim 87 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Garofano et al. in view of Frayne, U.S. Pat. No. 5,811,239.

9. I have reviewed Garafano et al.

10. I, or others under my direction, have performed experiments to attempt to determine the number of tape strippings that are required to attain a 50% loss or complete loss of adhesive power for adhesive tapes, or to attain a complete loss for stubs, using the method disclosed in Garofano et al. (Exhibit B).

11. The experiments show that for adhesive tapes at least 15 tape strippings, and on average for each subject at least 22 tape strippings, were required to attain a loss of adhesive power for adhesive tapes (Exhibit B).

12. The experiments show that for stubs at least 32 strippings, and on average for each subject at least 41 strippings, were required to attain a loss of adhesive power (Exhibit B).

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13. I further declare that all statements made herein of knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

9/8/03
Date

Nicholas Benson
Nicholas Benson, Ph.D.

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EXHIBIT B:

EXPERIMENTS SUPPORTING DECLARATION OF DR. NICHOLAS BENSON

Exhibit B

Determination of Longevity of Tape Adhesive Power After Multiple Applications to the Skin

Experiment#1

Introduction: The goal of this experiment is to determine the number of applications to skin, different types of commercial adhesives can withstand before losing adhesive power. Included in this test are two common packaging tapes and a "stub", an adhesive device used to collect gunshot residue. This series of experiments was prompted by the article by Garofano *et al.* (1996) entitled "PCR based analyses of epidermal cells found on adhesive tape." In this work, Garofano *et al.* teach that in order to collect sufficient material from the skin's surface, one must "press many times" the adhesive tape to the skin until adhesive power is lost. The experiments described here suggest that using the 3 adhesives recommended by Garofano *et al.*, the expression "many times" is probably greater than 25 applications.

Materials and Methods: Two common tapes were used in this experiment. One was Scotch (3M) brand Packaging Tape Super Strength and the second was Scotch brand Strapping Tape. These tapes were purchased from a nearby Staples Office Center. A third adhesive was in the form of stubs, which are used to collect gunshot residue from clothing and skin. Stubs were purchased from TRI-TECH, Inc. (Southport, NC; item # GSR-CCD). The stub adhesive tape comes attached to a plastic handling device, which weighs approximately 3.1 grams. Adhesive tapes were cut in the shape of rectangles approximately 1.5 cm². For the Scotch brand tapes, loss of 50% adhesive power was determined to have occurred if approximately 50% of the tape would no longer adhere to the skin as determined visually; for stubs, a 100% loss of adhesive power was used, the standard being if the stub could remain attached to the skin when the arm was inverted (stub hanging by adhesive force; i.e. if the stub fell, it was assumed to have completely lost adhesive power). Two healthy subjects were used in this experiment; tape was applied to the inner wrist and forearm area; 4 samples of each tape were used on each subject. Tapes were handled with forceps and applied to the skin by rubbing with the forceps. Stubs were pressed onto the skin forcefully and released.

Results and Discussion: The results of repeated application of tapes and stubs to the skin of the wrist or forearm are shown in Table 1.

Table 1. Number of applications required to exhaust approximately 50% of adhesive power.

Experiment	Number of Applications Required					
	Subject 1			Subject 2		
	Tape 1 ¹	Tape 2 ¹	Stub	Tape 1 ¹	Tape 2 ¹	Stub
1	> 25	> 25	> 25	23	12	> 25
2	24	>25	> 25	20	19	> 25
3	17	>25	> 25	22	22	> 25
4	> 25	22	> 25	15	23	> 25
Average	> 22.75	> 24.25	> 25	20	19	> 25

1. Tape 1 is Scotch Packaging Tape; Tape 2 is Scotch Strapping Tape; when 25 applications were reached, the experiment was halted to avoid entering the viable epidermis.

Table 1 demonstrates that on average at least 20 applications of a single tape is required to exhaust adhesive power and that frequently, adhesiveness was not lost after 25 applications. Stubs showed the greatest adhesive resiliency, never losing adhesion at application # 25. Because the stubs displayed such tenacity, on each subject we tested one stub for the number of applications required until the adhesive could not support the weight of the device when left hanging from the skin. For subject 1, 100% loss of adhesion occurred after 40 applications; for subject 2, 100% loss occurred after 58 applications.

In conclusion, to give meaning to the phrase "obtained pressing many times the adhesive tapes on the collecting surface until the adhesive power was lost," made by Garofano *et al.*, we have conducted the experiments described here. Our results suggest that there might be some subject-to-subject variability but that at least 19 applications of a single tape to the skin is required to exhaust 50% adhesive power. Furthermore, the device recommended as most effective, the "stub", did not lose strength for > 25 applications.

Experiment #2

Introduction: In an effort to more fully characterize the phrase "loss of adhesive power", we have performed an additional experiment where tape stripping was performed until the tape would not adhere to the skin. This was performed on tapes 1 and 2 only, because it is clear that "stubs" do not lose adhesive power until well after 30 applications.

Materials and Methods: Adherence was determined as follows: 1) the tape was applied to the inner forearm; 2) the arm was shaken several times; 3) adhesive power was deemed to be lost if the tape fell from the arm as a result of this shaking.

Results and Discussion: The results demonstrate that at least 15 tape strippings, and on average for a subject, at least 22 tape strippings are required to exhaust the adhesive

power of the tape (Table 2). The results also demonstrate that adhesive power can be affected by the individual skin type, and in some subjects it can require over 50 applications to exhaust the adhesive power of the tape.

Table 2. Number of applications required to completely exhaust adhesive power.

Experiment	Number of Applications Required by Subject			
	Subject 1 ¹		Subject 2 ¹	
	Tape 1 ²	Tape 2 ²	Tape 1 ²	Tape 2 ²
1	> 51	32	18	21
2	> 51	30	15	26
3	> 51	> 51	28	28
4	> 51	> 51	27	40
Average	> 51	> 41	22	29

1. Same subjects as in Table 1.
2. Tape 1 is Scotch Packaging Tape; Tape 2 is Scotch Strapping Tape; when 51 applications were reached, the experiment was halted to avoid entering the viable epidermis.